REMARKS

This paper is being submitted in response to the Notice of Non-Compliant Amendment, mailed on April 5, 2006. It incorporates much of the response to the non-final Office Action mailed September 28, 2005 (which is presumed to be entered), and addresses issues correctly raised by the Examiner in the April 5, 2006 Notice.

In the September 28, 2005 Action, claims 10-14 were rejected. Applicant respectfully traverses the rejection of the claims because the cited reference does not to disclose or suggest a needle/cannula combination comprising a needle with a piercing end and a cannula surrounding the needle with a clearance between the inner wall of the cannula and an outer wall of the needle as required by independent claim 10. Claims 11-14 depend from claim 10, and are allowable for the same reasons.

Claim 15 was added in the response to the September 28, 2005 Action and, as shown above has been changed to more clearly reflect the state of the cannula/needle combination prior to its use.

Claims 16 and 17 are independent claims presented in the response to the September 28, 2005 Action. Claim 16 is directed to a method of administering a substance using the needle/cannula combination of claim 10, wherein the needle has a sharpened end, the cannula surrounds the needle and there is a clearance between the inner wall of the cannula and the outer wall of the needle. Claim 17 is directed to a system for providing a needle/cannula combination comprising piercing means with a sharpened end and fluid delivery means surrounding the piercing means, wherein a clearance exits between the piercing and fluid delivery means.

Rejection Under 35 U.S.C. § 102

Claims 10, 11, 13 and 14 were rejected under 35 U.S.C. § 102(b) over Hattler (U.S. 4,846,791).

The § 102(b) rejection is traversed for at least the following reasons.

Hattler discloses that "a multi-lumen catheter is formed by first introducing one end of an expandable tube into the blood vessel. A divider is then inserted into the distal end of the tube and extends the length of the tube, thereby dividing the tube into a plurality of the separate lumens." (Hattler, Abstract.) Hattler further discloses that the assembly is performed in steps. At column 2, lines 35-38, Hattler states: "one end of an expandable tube is first introduced into a blood vessel through an opening in the wall of the blood vessel. A divider is subsequently inserted from the distal end of the tube and extends the length of the tube." Hattler further illustrates the multi-lumen catheter assembly where Hattler states:

> Figs. 4 through 8 illustrate the steps of installing a multi-lumen catheter in a blood vessel according to the present invention. Fig. 4 shows the first step in which the needle 20 and the end 12 of the catheter tube 10 are introduced into a blood vessel 40. The needle 20 punctures the wall 42 of the vessel and allows the end 12 of the catheter tube to be inserted through the needle into the interior of the blood vessel. A conventional hollow stainless steel needle of the type commonly used in the medical field is satisfactory for inserting the catheter tube into the blood vessel. . . . the needle 20 is then retracted out of the blood vessel, but the end of the catheter tube remains in place inside the blood vessel as shown in Fig. 5 . . . A divider 30 is then inserted into the catheter tube from the distal end 14 of the tube, as shown in Fig. 7. (Hattler, col. 4, lines 4-46.)

Therefore, needle 20 in Hattler surrounds catheter tube 10, and pierces the a blood vessel 40 wall 42 allowing catheter tube 10 to be inserted through the needle into the blood vessel. Hattler does not disclose the needle/cannula combination of claim 10, wherein a needle with a substantially sharpened piercing end is surrounded by a cannula to create a clearance between the inner wall of the cannula and an outer wall of the needle.

The divider 30 of Hattler is inserted into the catheter after the catheter has been inserted into the blood vessel. Therefore, the divider 30 is not a needle as recited in claim 10.

Hattler does not disclose each of the elements of independent claim 10 as required by § 102. Therefore, reconsideration and withdrawal of the § 102 rejection of the claims are requested.

Rejection Under 35 U.S.C. § 103

Claim 12 was rejected under 35 U.S.C. § 103(a) over Hattler.

Claim 12 depends from independent claim 10 and the § 103(a) rejection of claim 12 is traversed because of Hattler's fundamental failure to disclose or suggest the needle/cannula combination of claim 10, wherein a needle with a substantially sharpened piercing end is surrounded by a cannula to create a clearance between the inner wall of the cannula and an outer wall of the needle. Further, because Hattler discloses a multi-step process for assembling a multi-lumen catheter that requires the catheter to be inserted into the blood vessel via a needle surrounding the catheter, removing the needle, and then inserting the divider into the catheter, it teaches away from the recited invention, even if a catheter is in fluid communication with the Hattler arrangement.

Reconsideration and withdrawal of the § 103(a) rejection is requested.

New claims

Claim 15 is directed to the state of the cannula/needle combination prior to its use, i.e., that it is assembled prior to use. Support is found in the specification and drawings, for example, at least at page 2, line 20 wherein it is clear that the combined needle and cannula are inserted into the skin and subcutaneously. Claim 15 is allowable for at least the same reasons that claim 10 is, as set forth above.

Claims 16 and 17 are new independent claims, and are allowable for at least the same reasons that claim 10 is, as set forth above, further in view of their additional recitations.

Claim 16 is directed to a method of administering a substance using the needle/cannula combination of claim 10, wherein the needle has a sharpened end, the cannula surrounds the needle and there is a clearance between the inner wall of the cannula and the outer wall of the

needle. Support is found in the specification and drawings, for example, at least on page 2, lines 25-26, wherein it is clear that the combination is for subcutaneous administration of a substance.

Claim 17 is directed to a system for providing a needle/cannula combination comprising piercing means with a sharpened end and fluid delivery means surrounding the piercing means, wherein a clearance exits between the piercing and fluid delivery means. The claim is written in means format, clearly permitted under 35 U.S.C. § 112, paragraph six. The specification and drawings make it clear the needle has a sharpened tip for piercing skin, and that the cannula surrounds the needle, with a space or clearance between the needle and cannula. The specification supports that the combination is for the subcutaneous administration of a substance, for example, at least on page 2, lines 25-26 and at page 6, lines 23-26.

Conclusion

No additional fees are generated by the submission of the paper. However, the Commissioner is hereby authorized to charge any additional fees and/or credit any overpayments associated with this paper to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested. The Examiner is invited to telephone the undersigned if doing so will help expedite allowance.

Respectfully submitted,

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